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**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO. PCT/US04/16365	INTERNATIONAL FILING DATE 24 May 2004	PRIORITY DATE CLAIMED 23 May 2003
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TITLE OF INVENTION  
SURROGATE CELL GENE EXPRESSION SIGNATURES FOR EVALUATING THE PHYSICAL STATE OF A SUBJECT

APPLICANT(S) FOR DO/EO/US  
Catherine Clelland et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1.  This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2.  This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3.  This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4.  The US has been elected (Article 31).
5.  A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a.  is attached hereto (required only if not communicated by the International Bureau).
  - b.  has been communicated by the International Bureau.
  - c.  is not required, as the application was filed in the United States Receiving Office (RO/US).
6.  An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
  - a.  is attached hereto.
  - b.  has been previously submitted under 35 U.S.C. 154(d)(4).
7.  Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a.  are attached hereto (required only if not communicated by the International Bureau).
  - b.  have been communicated by the International Bureau.
  - c.  have not been made; however, the time limit for making such amendments has NOT expired.
  - d.  have not been made and will not be made.
8.  An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9.  An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10.  An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11.  An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12.  An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13.  A preliminary amendment.
14.  An Application Data Sheet under 37 CFR 1.76.
15.  A substitute specification.
16.  A power of attorney and/or change of address letter.
17.  A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
18.  A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19.  A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/558,277	INTERNATIONAL APPLICATION NO. PCT/US04/16365	ATTORNEY'S DOCKET NUMBER 02420/100M850-US1																																																																																																																				
20. <input checked="" type="checkbox"/> Other items or information: Petition for Extension of Time Under 37 CFR (1 page)																																																																																																																						
<p>The following fees have been submitted</p> <table border="1"> <tr> <td>21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) .....</td> <td>\$300</td> <td>CALCULATIONS</td> <td>PTO USEONLY</td> </tr> <tr> <td></td> <td>\$</td> <td></td> <td></td> </tr> <tr> <td>22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....</td> <td>\$0</td> <td>\$ 200.00</td> <td></td> </tr> <tr> <td>All other situations .....</td> <td>\$200</td> <td></td> <td></td> </tr> <tr> <td>23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....</td> <td>\$0</td> <td></td> <td></td> </tr> <tr> <td>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....</td> <td>\$100</td> <td>\$ 100.00</td> <td></td> </tr> <tr> <td>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....</td> <td>\$400</td> <td></td> <td></td> </tr> <tr> <td>All other situations.....</td> <td>\$500</td> <td></td> <td></td> </tr> <tr> <td colspan="2"><b>TOTAL OF 21, 22 and 23 =</b></td> <td>\$ 300.00</td> <td></td> </tr> <tr> <td colspan="2"> <input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). 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a.  A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b.  Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.

c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-0100. A duplicate copy of this sheet is enclosed.

d.  Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

**NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed or granted to restore the International Application to pending status.**

SEND ALL CORRESPONDENCE TO:

S. Peter Ludwig  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7770



SIGNATURE

Heather Morehouse Ettinger  
NAME

CUSTOMER NUMBER: 07278

51,658  
REGISTRATION NUMBER



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/558,277	Catherine Clelland	02420/100M850-US1
		INTERNATIONAL APPLICATION NO.
		PCT/US04/16365
		I.A. FILING DATE      PRIORITY DATE
		05/24/2004      05/23/2003
CONFIRMATION NO. 8267		
371 FORMALITIES LETTER		
 *OC000000020651931*		

Date Mailed: 10/02/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 11/23/2005
- Copy of the International Search Report filed on 03/01/2006
- Preliminary Amendments filed on 11/23/2005
- Information Disclosure Statements filed on 11/23/2005
- U.S. Basic National Fees filed on 11/23/2005
- Assignment filed on 11/23/2005
- Specification filed on 11/23/2005
- Claims filed on 11/23/2005
- Abstracts filed on 11/23/2005
- Drawings filed on 11/23/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **\$3100** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath

or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is **\$3940** for a Small Entity:

• **\$65** Surcharge.

- The specification and drawings contain more than 100 pages. Applicant owes **\$625** for **222** pages in excess of **100** pages for a small entity in compliance with 37 CFR 1.27.
- The application search fee has not been paid. Applicant must submit **\$50** to complete the search fee. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- The application examination fee has not been paid. Applicant must submit **\$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- Total additional claim fee(s) for this application is **\$ 3100**
  - **\$1000** for **10** independent claims over **3**.
  - **\$2100** for **84** total claims over **20**.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

KAREN M WILLIAMS

Telephone: (703) 308-9140 EXT 213

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/558,277	PCT/US04/16365	02420/100M850-US1